Exhibit G

BARD
PERIPHERAL
VASCULAR

April 25, 2003

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
9200 Corporate Boulevard
Rockville, MD 20850

Re: Abbreviated 510(k): Bard® Recovery® Filter System RF-048F

Dear Sir or Madam,

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, Bard Peripheral Vascular, a division of C. R. Bard, Inc., respectfully submits the enclosed **Abbreviated 510(k): Bard Recovery Filter System.** This submission proposes labeling modifications to the FDA cleared permanent cardiovascular intravascular filter device known as the Bard Recovery Filter System, Model RF-048F, 510(k) Number K022236.

Specifically, the proposed changes will modify the indications, current labeling limitation and Instructions for Use (IFU) to reflect instructions for percutaneous filter retrieval. **Please note that these proposed modifications do not change the original intended use of the predicate device.**

Bard believes that these proposed changes meet the requirements for review under the Abbreviated 510(k) process per the FDA's Final Guidance Document entitled , "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" dated March 20, 1998.

Bard Peripheral Vascular has not publicly disclosed or acknowledged the existence of this Abbreviated 510(k) to any individual outside its employ other than disclosure made under commercial agreements containing the appropriate safeguards for secrecy. As a result, Bard Peripheral Vascular requests that FDA keep and maintain confidential both the existence and the contents of the Special 510(k) in accordance with 21 CFR 812.38(a). Bard Peripheral Vascular also requests that FDA keeps and maintains confidential the contents of this letter.

If you have any questions or comments regarding this submittal, please contact me directly via telephone at 480-303-2640, facsimile at 480-449-2546 or via e-mail at mary.edwards@crbard.com.

Sincerely,

Mary Edwards
Vice-President
Regulatory and Clinical Affairs

Enclosures

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Indications for Use Section Change

Add the following information to the Indications for Use Section:

" Recovery filter may be removed according to the instructions supplied in the Section labeled: ***Optional Procedure for Filter Removal.***

"Data from removals in a 58 patient study suggests that the device can be safely removed (mean of 60 days; range 1-161 days)."

Precaution Section Change:

Remove the following wording from the Precaution Section:

"The safety and effectiveness of the Recovery filter as a retrievable or temporary filter have not been established".

Warning Section Change:

Pursuant to discussions with the Cardiovascular Division of January 14, 2003, the following information will be added to the Warning section under the Specific Removal Instructions. This information will be in bold and italic letters.

"Do not attempt to remove the Recovery Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena caval wall."

In addition, the following statement will be added:

"Do not attempt to remove the Recovery Filter with any device other than the recommended Recovery Cone."

Equipment Required Section Change

Add the following statement to the Equipment Required Section:

"If the physician chooses to percutaneously remove the Recovery® Filter, the Recovery Cone Removal System®[1] must be used and is available from C. R. Bard, Inc."

[1]The Recovery Cone is a manual surgical instrument for general use, Title 21 CFR Section 878.4800. Manual surgical instruments are Class I and exempt.